DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 10, 2015

Boston Scientific Limited
Ms. Lisa Mee
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K151253
Trade/Device Name: 2cm Peripheral Cutting Balloon Microsurgical Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 8, 2015
Received: May 12, 2015

Dear Ms. Mee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K151253

Device Name
2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter

Indications for Use *(Describe)*
The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510k Summary

Per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Lisa Mee Senior Specialist, Regulatory Affairs Phone: +353 91 406184 Fax: 763-494-2222 e-mail: Meel@bsci.com **Or** Melissa Sommerfeld Principal Specialist, Regulatory Affairs Phone : 763-494-1219 Fax: 763-494-2222 e-mail: Melissa.Sommerfeld@bsci.com
Date Prepared	8 May 2015
Proprietary Name	2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter
Common Name	Percutaneous Transluminal Angioplasty Dilatation Catheter
Product Code	LIT – Catheter, Angioplasty, Peripheral, Transluminal
Classification	Class II, 21 CFR Part 870.1250

Predicate Device(s)			
	2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter	K041993	Aug 16, 2004
	2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter	K070951	June 04, 2007

Device Description	The 2cm PCB is an Over-The-Wire (OTW) catheter packaged as sterile and intended for single use in a radiology suite/catheterization laboratory/operating room in conjunction with radiologic equipment for fluoroscopic imaging. The device consists of a double-lumen catheter with a non-compliant balloon attached at the distal tip. One of the lumens connects the Y-Adaptor to the proximal end of the outer shaft and the other connects the Y-Adaptor wire port extending from the wire lumen to the distal end of the balloon. The outer lumen is the balloon inflation lumen and is used to inflate and deflate the balloon during the procedure. The inner lumen is used to pass the catheter over a guidewire. The product is intended to pass a 0.018" (0.46 mm) guidewire. The catheter useable length (effective length) is measured from the distal end of the strain relief to the tip and is available in three sizes – 50 cm, 90 cm and 135 cm. Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel. The device is coated with MDX 4-4159 silicone coating.
Intended Use of Device	The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Indications for Use	The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae
Comparison of Technological Characteristics	The 2cm PCB incorporates substantially equivalent device materials, design, packaging, catheter configuration, fundamental technology, manufacturing processes, sterilization process, and intended use/indication for use as those in the Boston Scientific predicate devices, K041993 and K070951.
Performance Data	Bench testing was performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and therefore, these devices may be considered substantially equivalent to the predicate devices. The following in-vitro performance tests were completed: Balloon Compliance Balloon Rated Burst Pressure Balloon Multiple Inflation Balloon Deflation Time Introducer Sheath Compatibility Bond Strength Crossing Profile Freedom from Leakage Blade Attach Guide Catheter Compatibility Particulate Release The following biocompatibility tests were completed: In Vitro Cytotoxicity Guinea Pig Maximization Sensitization Intracutaneous Reactivity Acute Systemic Injection Materials Mediated Rabbit Pyrogen Ames Mutagenicity Mouse Lymphoma Assay Direct Contact Hemolysis Complement Activation C3a and SC5b-9 Assay Indirect Extract Hemolysis Partial Thromboplastin Time In Vitro Hemocompatibility USP Physicochemical Natural Rubber Latex
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed 2cm PCB Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific predicate 2cm PCB Dilatation Catheter.